

REMARKS

Status of the Claims

Claims 1-4, 7, 8, 11, 14, 21, 22 and 25-37 were pending. Claims 1-4, 7, 8, 11, 14, 21, 22 and 25-37 have been canceled without prejudice or disclaimer. Applicants respectfully reserve the right to pursue subject matter of the application as filed in a subsequent application(s) such as a divisional or continuation application. New claims 38-50 have been added. No new matter has been added. Claims 38-50 are currently under examination.

Claims Amendments

Claims 38-50 have been added. Support for these claims can be found throughout the application but at least at page 1 lines 16-22; page 7 line 21 to page 8 line 28; page 19 lines 16-29; page 23 lines 10-12; page 24 line 15 to page 32 line 10; page 39 line 17 to page 40 line 2; page 41 lines 1-23; and page 74 line 27 to page 77 line 20 and Claims 1-4, 7 and 11 of the application as originally filed.

Oath/Declaration Objection

The Applicants respectfully submit that a new Oath/Declaration is submitted along with this Request for Continued Examination and response. The Applicants respectfully request removal of the objection.

Rejection Under 35 U.S.C. §112, Maintained

On page 2, the Action asserts that "Claims 1, 3, 4 and 7 remain rejected and claims 25-37 are rejected under 35 U.S.C. 112 first paragraph..." The Applicants respectfully submit that new claims 38-50 do not recite the terms "according to" or "corresponding to." The Applicants respectfully submit that new independent claim 38 recites, "A composition consisting of N-terminally truncated galectin-3, wherein the truncated galectin-3 begins with Leu-7 of SEQ ID NO:1 and extends to Ile-143 of SEQ ID NO:1."

The Applicants respectfully submit that what is claimed in the instant application is a specific truncated galectin-3 molecule of 136 amino acids in length having the claimed activities. This molecule is novel and non-obvious and unexpectedly retains the activity of the entire galectin-3C

molecule. Appendix A is attached to this amendment and response in support of the claimed subject matter. The Applicants request removal of this rejection.

Rejection Under 35 U.S.C. §102, Maintained

On page 7, the Action asserts that “Claims 1-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Seetharaman et al (Journal of Biological Chemistry, 1998 273:13047-13052, hereinafter “Seetharaman”), as evidenced by SCORE search results 20070105_us-10-726-198-1.50 aligns.rup and LEGS_HUMAN alignment below) for the reasons set forth in section 17-pages 19-20...”

The Applicants respectfully note that new claims 38-50 overcome rejections based on Seetharaman. Seetharaman fails to recite wherein truncated galectin-3 is Leu-7 to Ile-143 of SEQ ID NO:1, as recited in new independent claim 38. The Applicants respectfully request removal of the rejection based on Seetjaraman.

New Grounds Objection/Rejection **Specification**

The Applicants respectfully submit that the references to the “Amendments to the Specification,” have been corrected to recite the locations of the originally filed specification (see page 2 of this response).

Claim Objections

On page 9, the Action recites “Claim 4 is objected to because...Galectin-3 is misspelled.” The Applicants respectfully submit that claim 4 has been canceled. The Applicants respectfully request removal of the objection.

Rejection Under 35 U.S.C. §112

On page 7, the Action asserts that “Claims 1, 3-4, 7, and 25-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement...” The Applicants respectfully submit that claims 1-4, 7, 8, 11, 14, 21, 22 and 25-37 have been canceled without prejudice or disclaimer. In addition, the Applicants respectfully submit that new claims

38-50 overcome the rejection based on 35 U.S.C. §112, first paragraph. New claim 38 recites “truncated galectin-3 begins with Leu-7 of SEQ ID NO:1 and extends to Ile-143 of SEQ ID NO:1.” The Applicants respectfully submit that new independent claim 38 does not recite “N-terminally truncated galectin-3 that begins with any of the amino acid residues from Gly-1 through Arg-22 of SEQ ID NO:1 and extends to any of the amino acid residues from Asp-134 through Ile-143 of SEQ ID NO:1...” The Applicants respectfully request removal of the rejection based on 35 U.S.C. 112, first paragraph.

In addition, the Applicants have attached Appendix A in support of the claimed subject matter. Appendix A, Figs. 1A and 1B illustrate the that N-terminally truncated Galectin-3 consisting of Leu-7 to Ile-143 of SEQ ID NO:1, was nearly identical in activity to that of the N-terminally truncated Galectin-3 of SEQ ID NO:1 consisting of Gly-1 to Ile-143 of SEQ ID NO:1. The binding was determined by fluorescence polarization analysis using a fluorescently-labeled carbohydrate ligand where there is increased polarization of the fluorescence-labeled molecule when it is bound to the protein. These data illustrate that the smaller of the two N-terminally truncated galectin-3 molecules, that both lack the multimerization region, retains carbohydrate binding functions as an inhibitor as well, or better than the larger N-terminally truncated protein.

On page 11, the Action recites “claim 35 is rejected under 35 U.S.C. 112 first paragraph, as failing to comply with the written description requirement...” The Applicants respectfully submit that claim 35 has been canceled, therefore rejection of claim 35 is now moot. The Applicants respectfully request removal of the rejection.

Rejection Under 35 U.S.C. §102

On page 12, the Action asserts that “Claims 1, 3, 4, 7, 27-34 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Gitt et. al. (J. Biol. Chem. 1995, 270:5032-5038, [hereinafter “Gitt”])...Gitt et al. teach rat galectin-5, which has a conservative substitution of isoleucine for valine at position 95 of SEQ ID NO:1, see Fig. 3...” The Applicants respectfully point out that the Applicants were unable to identify “Appendix 1” asserted by the Action on page 13.

The Applicants respectfully submit that Gitt fails to teach “A composition consisting of N-terminally truncated galectin-3, wherein the truncated galectin-3 begins with Leu-7 of SEQ ID

NO:1 and extends to Ile-143 of SEQ ID NO:1...”, elements of new independent claim 38. Moreover, Gitt fails to teach compositions of truncated forms of SEQ ID NO:1, for example, removing the amino terminal amino acids of SEQ ID NO:1 as in independent claim 38. The Applicants respectfully point to the third full paragraph of column 2 page 5037 of Gitt where Gitt recites “Of the other galectins that have been sequences, galectin-5 most closely resembles galectin-4 (Fig. 3)...This is especially true in the protein region defined by the exon that contains the majority of the conserved residues...and that is known to interact directly with the carbohydrate ligand...In this region, galectin-5 and the second domain of galectin-4 have 54% amino acid identity. In contrast, comparable domains of galectin-1, -2, and -3 show 31, 37, and 48 % identities, respectively...” As demonstrated in Fig. 3 of Gitt, galectin-5 is not galectin-3, much less a truncated form of galectin-3. Therefore, rejection under 35 U.S.C. § 102 based on Gitt is improper. The Applicants respectfully request removal of the rejection based on Gitt.

On page 14, the Action asserts that “Claims 1-4, 7, 25 and 27-34 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,967,021 (Panjawani et al. April 27, 2001, [hereinafter “Panjawani”])...given their broadest reasonable interpretation the claims are drawn to proteins that comprise the recited N-terminal truncations with varying identity to the sequence of SEQ ID NO:1 claimed...[Panjawani]...teaches SEQ ID NO:3, which has a conservative substitution of isoleucine for valine at position 95...and comprises a galectin-3 truncation from proline 6 to serine 134...” The Applicants respectfully submit that claims 1-4, 7, 25 and 27-34 and 37 have been canceled.

The Applicants respectfully submit that Panjawani fails to disclose, “A composition consisting of N-terminally truncated galectin-3, wherein the truncated galectin-3 begins with Leu-7 of SEQ ID NO:1 and extends to Ile-143 of SEQ ID NO:1,” elements of new independent claim 38. The Applicants respectfully submit that new claim 38 overcomes rejections based on Panjawani. Therefore, the Applicants request removal of the 35 U.S.C. §102(b) rejection based on Panjawani.

Additionally, claims 39-50 have all the elements of independent claim 38 plus additional elements, therefore rejection of claims 39-50 based on Panjawani are improper.

Rejection Under 35 U.S.C. §103

On page 15, the Action asserts that “Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over...[Panjawani]...as applied to claims 1-4, 7 and 27-38 above, and further in view of

Veronese (Biomaterials, March 2001, 22:405-17[, hereinafter “Veronese”])...Veronese teaches that PEG conjugation is performed for enhancing the therapeutic potential of proteins...”

The Applicants respectfully assert that new claims 38-50 overcome rejection based on Panjawani as presented above.

These 35 U.S.C. §103(a) rejections are based on Panjawani in combination with Veronese. Therefore, once the impropriety of using Panjawani in the rejections is established, all rejections based on Panjawani in combination with other references must fall.

A prima facie case of obviousness requires: 1) some suggestion or motivation, either in the references themselves or in the knowledge generally available in the art, to modify the reference or combine the teachings; 2) a reasonable expectation of success; 3) the prior art reference or references must teach or suggest all the claim limitations. As discussed above, Panjawani does not provide or suggest elements disclosed in new independent claim 38, notably “the truncated galectin-3 begins with Leu-7 of SEQ ID NO:1 and extends to Ile-143 of SEQ ID NO:l.” This deficiency is not made up for in Veronese.

Therefore, rejection under 35 U.S.C. §103(a) based on Panjawani in view of Veronese is improper. The Applicants respectfully request removal of the rejection.

Double Patenting Rejection

On page 16-17, the Action asserts that “Claim[s] 1-4, 7, 35, 36 and 28-36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of US Patent No. 6,770,622 in view of Veronese...”

The Applicants submit that new claims 38-50 overcome the double patenting rejection by recitation of “A composition consisting of N-terminally truncated galectin-3, wherein the truncated galectin-3 begins with Leu-7 of SEQ ID NO:1 and extends to Ile-143 of SEQ ID NO:l,” elements of new independent claim 38. Therefore, the Applicants request removal of the double patenting rejection.

New independent claim 38 is in condition for allowance. Claims 39-50 have all the elements of independent claim 38 plus additional elements, therefore claims 39-50 are also in condition for allowance.

CONCLUSION

For the reasons stated above, Applicants assert that claims 38-50 are in condition for allowance.

Respectfully submitted,

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